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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,139	06/12/2001	Peter Allen Revell	23530-0003	9561

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PILLSBURY WINTHROP, LLP  
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EXAMINER

ROBERT, EDUARDO C

ART UNIT PAPER NUMBER

3732

DATE MAILED: 06/24/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,139

Applicant(s)

REVELL ET AL. *on*

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-14 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 15-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Objections*

Claims 7-14 and 26 (see amendment filed on April 14, 2003) are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend or refer back to another multiple dependent claim, e.g. claim 6. See MPEP § 608.01(n). Accordingly, the claims 7-14 and 26 *have not been further treated on the merits*.

Claims 20 and 21 are objected to because of the following informalities:

In claim 20, line 1, "any one of" should be deleted.

In claim 21, line 1, "any one of" should be deleted.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 25 applicants appear to recite a method step of making the bone implant, e.g. "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition" and this is indefinite because the general rule is that a product claim violates 35 USC 112, second paragraph, if structure is described by the process of

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making rather than in structural terms and the structure is capable of description in structural terms. *In re Johnson*, 157 USPQ 106 (CCPA 1974). It is noted that the applicant's apparatus, i.e. "bone implant" is capable of being describe in structural terms, e.g. reciting the molecular structure of the bioactive material with the ions incorporated, etc.

In claim 25, line 5, "the surface atomic layers" lacks a prior antecedent.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz (Reference "B" on PTO-1449).

Constantz discloses an implant having a hydroxyapatite coating that the coating can have incorporated therein a variety of ions, as required (see col. 2, lines 64-68). It is noted that the ions comprise fluorine ions. With regard to the method step recitation in claim 1, "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition", it is noted that the method of forming the device is not germane to the issue of

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patentability of the device itself. Therefore, this limitation has not given patentable weight. Moreover, the device of Constantz, et al. appear to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with **evidence** establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Claims 1, 2, 15, 16, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Natasi, et al.

Natasi, et al. disclose an implant having a hydroxyapatite coating that the coating can have incorporated therein a ion (see abstract). Natasi, et al. disclose that any ions might be utilized in the ion implantation process (see col. 5, lines 25-27), thus this statement include ions of groups IIA, IVA, VIIA and transition elements. With regard to the method step recitation in claim 1, "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition", it is noted that the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not given patentable weight. However, it is noted that Natasi, et al. disclose that the ions are incorporated via ion beam implantation.

Applicant is reminded that an anticipation under 35 U.S.C. 102(b) or 102(e) is established when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data System, Inc.*, 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984). Furthermore, it is well settled that the law of anticipation does not required that the reference teach what appellant is teaching or has disclosed, but only that the claims on appeal "read on" something disclosed in the reference, i.e.

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all limitation of the claims are found in the reference. *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently discloses that element or limitation. *Standard Havens Products Inc. v. Gencor Industries Inc.*, 953 F.2d 1360, 21 USPQ 2d. 1321 (Fed. Cir. 1991).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz (Reference "B" on PTO-1449).

Constantz discloses the claimed invention except for the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm (claims 3 and 25), or up to a maximum depth of 150 nm (claim 4), or up to a maximum depth ranging up to approximately 100 nm (claim 5), or the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface (claim 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Constantz with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, or up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or

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the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 3-6, 17-20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nastasi, et al.

Nastasi, et al. discloses the claimed invention except for the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm (claims 3, 17, and 25), or up to a maximum depth of 150 nm (claims 4 and 18), or up to a maximum depth ranging up to approximately 100 nm (claims 5 and 19), or the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface (claims 6 and 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Nastasi, et al. with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, or up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments filed on April 14, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that "the product resulting from ion incorporation by ion beam implantation or cathodic arc deposition can only be suitably describe in terms of these methods", it is noted that the product resulting from ion incorporation and to what claim 1 is directed, i.e. "bone implant", is capable being described in structural terms, e.g. by reciting the molecular structure of the bioactive material with the ions incorporated, etc.

In response to applicant's argument that "alteration in structure can only be suitably described by the technique itself rather than the resulting structure", it is noted that claim 1 is directed to an "apparatus" claim, i.e. the resulting structure, not to a method or technique of how to get the resulting structure. It appears that applicants are more interest in "how" to alter the structure than to the specific resulting structure or apparatus, thus applicant is advised to pursue this with a method of making claim.

In response to applicant's argument that "Constantz does not disclose a method of incorporating ions into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition", it is noted that the claims rejected by Constantz are directed to "apparatus" claims, i.e. bone implant, not to a method. Moreover, as stated above in the 102 rejection, the device of Constantz, et al. appear to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with **evidence** establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). **Mere arguments by counsel cannot take the place of evidence.** In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.



In response to applicant's argument that Nastasi, et al. do not disclose incorporating ions from one or more groups IIA, IVA, VIIA and transition elements", it is noted that Nastasi, et al. disclose that "other ions may be utilized in the ion implantation", thus clearly this broad recitation will encompass within its scope ions from one or more groups of IIA, IVA, VIIA and transition elements.

In response to applicant's argument that the Nastasi, et al. addresses a different problem than the one of the current application, it is noted the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Applicant's arguments with regard to claims 3-6, 17-20, and 25 do not overcome the rejections applied thereto, since applicant has not provide any convincing showing that these are nothing more than optimum or workable values as asserted by the examiner. Applicant has not provided any showing that such limitations are "critical". *In re Cole*, 140 USPQ 230 (CCPA 1964); *In re Kuhle*, 188 USPQ 7 (CCPA 1975); *In re Davies*, 177 USPQ 381 (CCPA 1973). **Mere arguments by counsel cannot take the place of evidence.** *In re Cole*, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); *In re Walters*, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

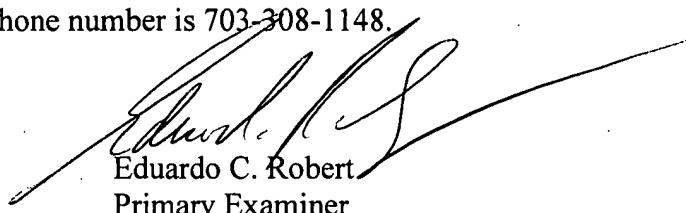
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

A handwritten signature in black ink, appearing to read 'Eduardo C. Robert', is written over the printed name and title.

Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C. Robert  
June 21, 2003